UTAH MEDICAL PRODUCTS INC.

K123310

JAN 23 2013



# 8.0 510(k) Summary

| | |
|---|---|
| 510(k) Owner: | Utah Medical Products, Inc. |
| Address: | 7043 South 300 West<br>Midvale, UT 84047 USA |
| Telephone No.: | (801) 566-1200 |
| Fax No.: | (801) 566-2062 |
| Contact: | Ben Shirley, VP of Quality Assurance & Product Development |
| Date: | 20 November 2012 |
| Trade Name: | FINESSE |
| Common Name: | Electrosurgical and Suction Unit |
| Classification: | Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400, Product Code GEI); and<br>Gynecologic electrocautery and accessories (21 CFR 884.4120, Product Code HGI). |
| Predicate Device: | Finesse I (K951032)—Utah Medical Products, Inc.; and<br>Finesse IEC/601 (K941251)—Utah Medical Products, Inc. |
| Device Description: | The Finesse 3rd Generation combines a high-quality, class I type BF electrosurgical generator and a smoke evacuation system into a single compact unit. This integrated system is designed to perform low-power excision and coagulation procedures of short duration. The Finesse 3rd Generation is comprised of two models: FINESSE+ and FINESSE II+. The FINESSE II+ is identical to the FINESSE+, but does not have as many user adjustable features. |



UTAH MEDICAL PRODUCTS, INC • 7043 South 300 West • Midvale, Utah 84047-1048 • 801/566-1200 • FAX# 801/566-2062
www.utahmed.com

Indications for Use: The FINESSE+ and FINESSE II+ are intended to deliver high frequency electrical current for surgical procedures that can be performed with monopolar cutting and/or coagulation of tissue. One intended use of the FINESSE+ and FINESSE II+ systems is Loop Excision of the Transformation Zone (LETZ®).

Comparison to Predicate Device: The Finesse 3rd Generation is substantially equivalent in design, composition, and function to the predicate device "Finesse" built and marketed by UTMD under 510(k) #K941251 (Product Code HGI) and #K951032 (Product Code GEI). In order to meet the requirements of AAMI / ANSI ES 60601-1:2005 and AAMI / ANSI / IEC 60601-2-2:2009, the method of protection against excessive output was improved and the ability to interface with a monitoring neutral electrode was added to the Finesse 3rd Generation. The technological characteristics, methods of use, intended use, indications for use and contraindications are the same as the predicate devices.

Performance Data: Laboratory testing was conducted to certify the Finesse 3rd Generation's compliance with the requirements of ANSI / AAMI ES 60601-1:2005, AAMI / ANSI / IEC 60601-1-2:2007, and ANSI / AAMI / IEC 60601-2-2:2009. The operating principle of the Finesse 3rd Generation is identical to the predicate device.

Ben Shirley
VP of Quality Assurance & Product Development
Utah Medical Products, Inc.



UTAH MEDICAL PRODUCTS, INC • 7043 South 300 West • Midvale, Utah 84047-1048 • 801/566-1200 • FAX# 801/566-2062
www.utahmed.com

Verification:

- This summary includes only information that is also covered in the body of the 510(k).
- This summary does not contain any puffery or unsubstantiated labeling claims.
- This summary does not contain any raw data, i.e., contains only summary data.
- This summary does not contain any trade secret or confidential commercial information.
- This summary does not contain any patient identification information.

Ben Shirley
VP of Quality Assurance & Product Development
Utah Medical Products, Inc.



UTAH MEDICAL PRODUCTS, INC • 7043 South 300 West • Midvale, Utah 84047-1048 • 801/566-1200 • FAX# 801/566-2062
www.utahmed.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Utah Medical Products
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, Northwest
Buffalo, Minnesota 55313

January 23, 2013

Re: K123310
Trade Name: UTMD Finesse 3rd Generation; Electrosurgical Generator and Smoke Evacuator System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, HGI
Dated: January 08, 2013
Received: January 09, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 7.0 Indications for Use Statement

**510(k) Number:** K123310

**Device Name:** UTMD Finesse 3rd Generation; Electrosurgical Generator and Smoke Evacuator System

**Indications for Use:** The FINESSE+ and FINESSE II+ are intended to deliver high frequency electrical current for surgical procedures that can be performed with monopolar cutting and/or coagulation of tissue. One intended use of the FINESSE+ and FINESSE II+ systems is Loop Excision of the Transformation Zone (LETZ®).

☒ Prescription Use (Part 21 CFR 801 Subpart D) AND/OR ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Yen
2013.01.23 12:57:49 -05'00'

Division of Surgical Devices
510(k) Number: K123310